SentreHEART Announces Initial Clinical Use of the LARIAT® with EpiRAIL™ Procedure for Left Atrial Appendage Exclusion

REDWOOD CITY, CA- SentreHEART, Inc., announced it has successfully completed nine First-In-Human procedures utilizing the LARIAT® with EpiRAIL™ at John Paul II hospital in Krakow, Poland. The LARIAT with EpiRAIL is an epicardial-only, percutaneous approach to complete and permanent closure of the left atrial appendage (LAA) in patients with atrial fibrillation and increased risk of stroke. All cases were performed by Dr. Krzyzstof Bartus of John Paul II Hospital and Dr. Randy Lee of UCSF. The EpiRAIL received CE mark clearance and will undergo continued evaluation at European centers.

The LARIAT is differentiated from all other percutaneous LAA closure devices in Europe being the only non-implant solution for complete and permanent exclusion of the LAA. Using a non-surgical, image guided approach, the LARIAT with EpiRAIL enables clinicians to precisely deliver a pre-tied suture loop to the base of the LAA from the outside that leaves no metal or foreign material inside of the heart. Over time, the LAA will disappear and no longer be a source for blood clots in patients with atrial fibrillation. The LARIAT with EpiRAIL eliminates the requirement of a transseptal catheterization in order to enter the left atrium of the heart. Instead, a single access approach is utilized to deliver the LARIAT using the innovative EpiRAIL vacuum stabilization system.

“The LARIAT with EpiRAIL is a true game changer in the area of percutaneous LAA closure,” stated Dr. Bartus. “The benefits we have seen in this early experience is the elimination of transseptal catheterization, no manipulation within the heart that may lead to thrombus formation, and no use of contrast in the heart which will be a benefit to patients with renal disease.”

Patients with atrial fibrillation (AFib) are five times more likely to suffer a stroke than those with normal sinus rhythm[1]. The LAA is recognized as the primary source

of stroke-causing blood clots originating from the heart in patients with non-valvular atrial fibrillation[2]. By closing the LAA, it is believed the incidence of stroke may be reduced thus eliminating the requirement for life-long anticoagulation.

"The initial experience with the EpiRAIL approach with the LARIAT device for percutaneous LAA closure has been outstanding and is a revolutionary advancement. Epicardial visualization of the LAA via the EpiRail approach allows for the LARIAT snare to easily be passed over the LAA resulting in a faster and safer LAA closure procedure," says Dr. Lee.

SentreHEART, the manufacturer of the LARIAT® Suture Delivery Device, is presently conducting the prospective, multi-center, randomized controlled Trial known as the aMAZE Trial (https://amazetrial.com) in up to 65 centers within the United States. The Trial is a superiority design and intends to demonstrate the LARIAT procedure for LAA closure, when used in adjunct with subsequent Pulmonary Vein Isolation (PVI) catheter ablation, will lead to a reduced incidence of recurrent AFib compared to PVI alone in those patients that suffer from drug-refractory, persistent and long-standing persistent AFib.

Unlike LAA implant solutions for AFib, the aMAZE Trial seeks to potentially treat an underlying disorder of AFib by mechanically and electrically isolating the base of the LAA in a single step using the percutaneous, non-implant LARIAT suture delivery device.

Studies have demonstrated the LARIAT not only closes the LAA mechanically[3] but may also isolate electrical activity[4] within the LAA. Having a non-implant option that may both electrically and mechanically isolate the LAA is a potentially important addition to the treatment armamentarium for clinicians treating patients with persistent or longstanding persistent AFib.

Learn more about the aMAZE Trial, including patient eligibility, at the following: https://clinicaltrials.gov/ct2/show/NCT02513797 and https://amazetrial.com

Clinicaltrials.gov Identifier: NCT02513797
U.S. FDA IDE #G150107

About SentreHEART, Inc.
SentreHEART is a privately owned medical device company based in Redwood City, CA. Founded in 2005, SentreHEART has developed innovative technology for remote delivery of suture for closure of anatomic structures including the left atrial appendage.

1. "Atrial Fibrillation Fact Sheet." Centers for Disease Control and Prevention. http://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_atrial_fibrillation.htm.

2. Blackshear JL, Odell JA. Appendage obliteration to reduce stroke in cardiac surgical patients with atrial fibrillation. Ann Thorac Surg. 1996;61:755-759.

3. Bartus K, et al. Percutaneous Left Atrial Appendage Suture Ligation Using the LARIAT Device in Patients with Atrial Fibrillation. J Am Coll Cardiol 2013 Jul 9; 62(2):108-18.

4. Han F, et al. The Effects of LAA Ligation on Electrical Activity. Heart Rhythm. 2014 May; 11(5):864-70.

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